Iowa Board of Pharmacy

Frequently Asked Questions: COVID-19

Last update: August 17, 2020

The Iowa Board of Pharmacy is committed to protecting the health and safety of Iowans during the current COVID-19 pandemic. The Board and staff have received many questions relating to the pandemic and its effect on the provision of pharmacy services in Iowa. On March 22, 2020, Governor Kim Reynolds issued a Proclamation of Disaster Emergency in which she temporarily suspended a number of rules relating to licensing issues with the goal of increasing the availability of health care providers in the practice of pharmacy. On March 27, 2020, the Board issued a Response to the Governor's Proclamation which provided further guidance to affected licensees.

In addition to the Governor's Proclamation, the Board published its Statement on Board Enforcement during the COVID-19 Pandemic to provide the Board's intention of exercising risk-based enforcement discretion as it relates to rules that apply to the practice of pharmacy, with the exception of rules relating to controlled substances.

On April 2, 2020, Governor Reynolds issued an additional Proclamation of Disaster Emergency in which she extended the licensing regulatory relief from the March 22 Proclamation and authorized new regulatory relief relating to drug product selection, pharmacist license reciprocity, and initial pharmacist licensure. As required by Governor Reynolds, the Board issued this Guidance relating to the temporary suspension of administrative rules in these areas which directly impact the Board of Pharmacy and 657 Iowa Administrative Code.

On April 27, 2020, Governor Reynolds signed another Proclamation of Disaster Emergency in which she extended the licensing regulatory relief from prior Proclamations to continue through May 27, 2020. The Board issued this Response to provide information to licensees about the implementation of the Governor's Proclamation. During its May 5 meeting, the Board discussed and voted on additional guidance relating to pharmacist continuing education and emergency licensure of graduated pharmacist-interns. As noted in the FAQs below, the Board determined no action would be necessary at this time to extend the deadline for completion of or reduce the number of required continuing education hours for pharmacist renewal by July 1. The Board further provided this Guidance relating to the granting of emergency pharmacist licenses.

On May 26, 2020, Governor Reynolds signed another Proclamation of Disaster Emergency in which she extended the licensing regulatory relief from prior Proclamations to continue through June 25, 2020. The Board issued this Response to provide information to licensees about the continuation of the regulatory relief.

On June 25, 2020, Governor Reynolds signed another Proclamation of Disaster Emergency in which she extended the licensing regulatory relief from prior Proclamations to continue through July 25, 2020. The Board issued this Response to provide information to licensees about the continuation of the regulatory relief.

On July 24, 2020, Governor Reynolds signed another Proclamation of Disaster Emergency in which she extended the licensing regulatory relief from prior Proclamations to continue through August 23, 2020. The Board issued this Response to provide information to licensees about the continuation of the regulatory relief.

This document intends to provide information and answers to specific questions that the Board has received or anticipates receiving. These FAQs are being provided to all licensees and registrants. This information can also be found on the Board's website at pharmacy.iowa.gov on the home page under the "Health Resources and Links" section. **Please note that the Board cannot anticipate every scenario that might occur as it relates to adjusting pharmacy operations as a result of COVID-19 and the challenges that the novel coronavirus may present.** The Board anticipates pharmacists will exercise prudent professional judgment in determining how best to modify practice to provide quality pharmaceutical care to Iowans while protecting the public and pharmacy personnel.

Additional questions that are not addressed in this document may be directed to Board Compliance Staff. Staff will make every effort to provide a timely response.

The COVID-19 pandemic continues to evolve. The Board anticipates continued submission of additional questions. As such, this document will be updated as additional information warrants. Please continue to check the Board's website for updated versions. New questions or updated answers are in red. Updates to questions relating to the extension of regulatory relief with extended Governor Proclamations are not highlighted.

GENERAL INFORMATION / RESOURCES

- Iowa Board of Pharmacy
  - Compounding Garb Limitations
  - Statement on Board Enforcement during COVID-19 Pandemic
  - Response to Governor's March 22 Proclamation (March 27, 2020)
  - Response to Governor's April 2 Proclamation (April 6, 2020)
  - Response to Governor's April 27 Proclamation (April 29, 2020)
- Iowa Governor Kim Reynolds
  - State of Public Health Disaster Emergency (March 17, 2020)
  - Proclamation of Disaster Emergency (March 22, 2020)
  - Proclamation of Disaster Emergency (April 2, 2020)
  - Proclamation of Disaster Emergency (April 27, 2020)
  - Proclamation of Disaster Emergency (May 26, 2020)
  - Proclamation of Disaster Emergency (June 25, 2020)
  - Proclamation of Disaster Emergency (July 24, 2020)
- Iowa Department of Public Health
  - Novel Coronavirus (COVID-19)
  - Isolation Guidance for Essential Services Personnel
  - Isolation Guidance for Iowans
  - What is Self Isolation?
  - Iowa Statewide Emergency Registry of Volunteers (i-SERV)
  - COVID-19 Outbreak Guidance for Businesses (April 8, 2020)
- U.S. Centers for Disease Control and Prevention (CDC)
  - Coronavirus (COVID-19)
  - Coronavirus Disease 2019 (COVID-19) Hospital Preparedness Assessment Tool
  - Interim US Guidance for Risk Assessment and Public Health Management of Healthcare Practitioners with Potential Exposure in Health Care Setting to Patients with Coronavirus Disease 2019 (COVID-19) (March 7, 2020)

    - Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19 (Interim Guidance) (March 16, 2020)
    - Considerations for Pharmacies During the COVID-19 Pandemic (April 3, 2020)
    - Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19 (April 8, 2020)
    - Considerations for Pharmacies during the COVID-19 Pandemic (April 14, 2020)
    - Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies during the COVID-19 Response (Updated May 28, 2020)
- Critical Point
    - Critical Point Peer Network
- National Center for Biotechnology Information, US National Library of Medicine
    - WHO Guidelines on Hand Hygiene in Health Care (hand sanitizer formulation)
- United States Pharmacopeia (USP)
    - Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic (Updated March 25, 2020)
    - USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic
    - USP COVID-19 Response Hand Sanitizer Information (May 4, 2020)
- U.S. Drug Enforcement Administration (DEA)
    - COVID-19 Information Page
    - DEA Guidance re: Oral Emergency CII Prescriptions (March 27, 2020)
    - DEA Letter to Hospitals/Clinics, Manufacturers, and Distributors (April 10, 2020)
    - DEA Letter to Practitioners/Dispensers re: Temporary Suspension of 5% Distribution Regulation (April 13, 2020)
- U.S. Food and Drug Administration (FDA) (Updated August 17, 2020)
    - Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits (March 20, 2020)
    - Coronavirus (COVID-19) Update: FDA Provides Update on Patient Access to Certain REMS Drugs during COVID-19 Public Health Emergency (March 22, 2020)
    - Coronavirus (COVID-19) Update: FDA Helps Facilitate Veterinary Telemedicine During Pandemic (March 24, 2020)
    - Coronavirus (COVID-19) Update: FDA Takes Action to Increase U.S. Supplies through Instructions for PPE and Device Manufacturers (March 24, 2020)
    - Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-based Hand Sanitizer Products during the Public Health Emergency (COVID-19) Guidance for Industry (March 25, 2020)
    - FDA adds Hydroxychloroquine to Category 1 for Compounding with Bulk Drug Substances under 503B (March 25, 2020)
    - Emergency Use Authorization for Use of Chloroquine or Hydroxychloroquine Supplied from the SNS for Treatment of COVID-19 (March 28, 2020)
    - Safely Using Hand Sanitizer (March 30, 2020)
    - Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions (March 30, 2020)

    - Coronavirus (COVID-19) | Drugs
    - Coronavirus (COVID-19) Update: Serological Tests (April 7, 2020)
    - Summary of Best Practices for Retail Food Stores, Restaurants, and Food Pick-Up/Delivery Services During the COVID-19 Pandemic (April 10, 2020)
    - Temporary Policy Regarding NonStandard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (April 10, 2020)
    - Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization to Decontaminate Millions of N95 Respirators (April 12, 2020)
    - Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (April 20, 2020)
    - Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency (April 22, 2020)
    - Coronavirus (COVID-19) Update: FDA Reiterates Importance of Close Patient Supervision for 'Off-Label' Use of Antimalarial Drugs to Mitigate Known Risks, Including Heart Rhythm Problems (April 24, 2020)
    - Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency (April 30, 2020)
    - Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment (May 1, 2020)
    - Temporary Policy Regarding NonStandard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (May 14, 2020)
    - Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised May 21, 2020)
    - Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised May 21, 2020)
    - Temporary Policy for Manufacture of Alcohol for Incorporation Into AlcoholBased Hand Sanitizer Products During the Public Health Emergency (COVID-19) (Updated June 1, 2020)
    - Medical Device Shortages During the COVID-19 Public Health Emergency (August 14, 2020) (August 17, 2020)
- U.S. Environmental Protection Agency (EPA)
    - EPA Announces Enforcement Discretion Policy for COVID-19 Pandemic (March 26, 2020)
- U.S. Occupational Safety and Health Administration (OSHA)
    - Guidance on Preparing Workplaces for COVID-19 (March 2020)
- U.S. Dept of Health and Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR)
    - COVID-19: 2019 Novel Coronavirus Disease

- Iowa Poison Control Center
    - POISON ALERT: Serious Toxicity from Chloroquine and Hydroxychloroquine (March 25, 2020)
- Iowa Pharmacy Association (IPA)
    - COVID-19 Resources
- National Community Pharmacists Association
    - NCPA Coronavirus Information (March 31, 2020)
- American Pharmacists Association (APhA)
    - COVID-19 Resources and Training For You
    - COVID-19: Demystifying Testing for the SARS-CoV-2 Virus (April 8, 2020)
    - COVID-19: Practice Resources
- Pharmacist's Letter
    - TPL Therapeutic Substitution resources
- The Joint Commission
    - Coronavirus (COVID-19) Information and Resources
- National Council for Prescription Drug Programs (NCPDP)
    - NCPDP Emergency Preparedness Information (May 2020)
- Centers for Medicare & Medicaid Services (CMS) (Updated August 17, 2020)
    - Medicare Pharmacies and Other Suppliers May Temporarily Enroll as Independent Clinical Diagnostic Laboratories to Help Address COVID-19 Testing (May 8, 2020)
    - CMS and CDC announce provider reimbursement available for counseling patients to self-isolate at time of COVID-19 testing (July 31, 2020)

OPERATING OR CLOSING PHARMACIES

Question: Can our pharmacy adjust our hours of operation?

Answer: Yes. The Board's rules do not mandate that your pharmacy be open a minimum number of hours or days. It is highly recommended that you provide updated information as far in advance and to the extent possible to your patients. For a telepharmacy operation, the hours of operation of the telepharmacy site are required to be in the agreement with the managing pharmacy, so the sites are encouraged to be in communication with each other and patients to modify hours of operation.

Question: Can our pharmacy convert to a closed-door or delivery-only operation temporarily?

Answer: Yes. The Board's rules do not require a general pharmacy license to be open to the public. The pharmacy is encouraged to provide advanced notice, to the extent possible, to the pharmacy's patients and prescribers, as well as signage on the pharmacy exterior to provide information to customers.

Question: What are the Board's expectations if a pharmacy has to close entirely?

Answer: If a pharmacy is going to close entirely:

- The pharmacist-in-charge or owner should notify Board staff prior to the closing, or as soon as possible after closing (if prior notification is not reasonably possible).
- Patients should be notified prior to the closing, or as soon as possible after closing (if prior notification is not reasonably possible). The notification should provide information about how patients can have their prescription(s) transferred or instruct that they will need to obtain new prescriptions from their provider to be filled at a different pharmacy.
- Clinics, hospitals, and prescribing practitioners from which the pharmacy receives prescriptions should be notified to the extent reasonably possible.
- If the pharmacy plans to reopen at a later date, the above notifications should include the anticipated reopening date.

Question: Does the Board have recommendations for pharmacies that continue operating?

Answer: In addition to the recommendations elsewhere in this document, pharmacies should consider the following actions when staff are working in a pharmacy that remains open to the public:

- Encourage customers to buy over-the-counter medications (without hoarding) and to refill prescriptions before they become exposed to or infected with COVID-19 (keeping in mind that *individuals do not always know if they have been exposed or infected*).
- Establish a process for reducing or eliminating the amount of time customers wait in line to pick up filled prescriptions - especially those who are at most risk. Suggestions include:
    - Maximize (or require) use of drive-through window(s) or implement curbside pick up options
    - Initiate an appointment process for prescription pick up
    - Limit the number of patients that can be in the pharmacy area at one time
    - Initiate prescription delivery services (note that prescription delivery is a task that does not require Board registration)
- Implement infection control procedures:
    - When possible, staff should maintain a distance of 6 feet from patients or other staff members; some pharmacies have placed tape on the floor in 6-foot increments to distance customers from each other
    - Require patient mask use if observed to be symptomatic
        - Updated CDC Guidance, issued April 14, 2020, recommends “everyone entering the pharmacy should wear a face covering, regardless of symptoms. Cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance.”
        - The updated CDC guidance also recommends pharmacy personnel “should always wear a facemask while they are in the pharmacy for source control.”
    - Regularly clean and disinfect counters, waiting areas, and other spaces - especially where public interaction occurs.
    - Place alcohol-based hand sanitizer with at least 60% isopropyl alcohol or ethyl alcohol next to the cash register or check-out area so people can sanitize their hands after using common items, like pens.

    - Staff should wash hands with soap and warm water frequently and for at least 20 seconds. (You can download and print: IDPH Hand Washing Sign)
    - Staff should avoid touching eyes, nose, and mouth.
    - Staff should cover coughs and sneezes with a tissue and discard.
    - Regularly monitor all staff for illness. Staff members should stay home if they have symptoms of any respiratory infection.
    - Some businesses have put in place temporary barriers to limit transmission when customer distance cannot be at least 6 feet, such as plexiglass barriers and hanging clear plastic shower liners.
    - Consider limiting the number of patrons allowed in the store at any given time.
    - Updated CDC Guidance (April 14, 2020) and Iowa Department of Public Health PPE Shortage Order (April 9, 2020) direct pharmacies to temporarily discontinue provision of clinical preventive services, such as immunizations to limit potential spread of the virus as well as to preserve PPE.
- Identify staffing contingency plans sooner than later to identify temporary staff that could be called to work in the event existing staff is unavailable due to illness
    - Note that an individual tasked with prescription delivery alone is not required to be registered with the Board.
    - Note that the Governor's March 22 Proclamation (continued in subsequent Proclamations) permits the practice of a pharmacist with an inactive or lapsed license so long as the license has not been inactive or lapsed for more than five years. This permission does not extend to revoked or voluntarily surrendered licenses or registrations.
- Ensure pharmacy policies and procedures are current and readily available should temporary personnel be utilized and current staff is not available to provide needed information.
- Review Considerations for Pharmacies During the COVID-19 Pandemic issued April 3, 2020 for additional recommendations. Updated April 14, 2020: Considerations for Pharmacies During the COVID-19 Pandemic.

Question: Can an out-of-state pharmacy which is NOT licensed in Iowa ship prescriptions to patients located in Iowa without obtaining a license?

Answer: At this time, no. A pharmacy intending to ship prescriptions to Iowans in this state must continue to hold an Iowa pharmacy license. If an unlicensed, nonresident pharmacy is located in a community along an Iowa border and has an existing patient who normally presents in person to pick up their medications, but is currently isolating due to COVID-19, the pharmacy may temporarily mail or deliver the medications to their patient during the period of the state of emergency.

Question: Can an out-of-state wholesaler or drug distributor which is NOT licensed in Iowa ship prescription drug products into Iowa?

Answer: At this time, no. A distributor intending to distribute drug products into this state must hold an appropriate license. A manufacturer must hold a Limited Distributor license while a

wholesaler (if it meets the federal definition of a wholesaler) must hold a Wholesale Distributor license. Under the Board's current position to exercise risk-based enforcement discretion, it is possible the board would consider expedited licensure to an applicant which may not meet all the Board's requirements identified in rule (e.g., VAWD accreditation), but at this time the Board has not been made aware of any particular supply issues that would warrant such extreme action. The Board is acutely concerned about the potential for black or gray market operations which may be engaged in the distribution of counterfeit drug products and will take all necessary actions to prohibit those operations in Iowa.

PRESCRIPTION DISPENSING / DELIVERY

Question: Our pharmacy provides a home delivery service. Our drivers may be exposed to COVID-19 if they have to enter a home to get someone to sign for the delivery of the prescription. Do we have to get the signature?

Answer: No. The Board's rules do not require a patient's signature at delivery. The pharmacy may need to inquire with the patient's third-party payer to determine signature requirements and, if there are, if the payer will temporarily relax the requirement. The Iowa Pharmacy Association may also have additional information as it relates to insurer issues during this pandemic. Visit Iowa Pharmacy Association's website for more information. Additional information relating to Medicare and CMS actions can be found at CMS Newsroom.

Question: Our pharmacy sometimes delivers filled prescriptions to the workplace of the patient or to a caregiver's workplace. Do the filled prescriptions have to be delivered directly to the patient or caregiver, or can they be dropped off at a central location, like a reception desk?

Answer: The Board recently adopted an amendment to 657 IAC 8.15 for delivery of prescriptions. The amended rule, effective April 29, says:

> **657—8.15(155A) Delivery of prescription drugs and devices.** A prescription order may be delivered to a patient at any location licensed as a pharmacy. Alternatively, a pharmacy may use the mail, a common carrier, or personal delivery to deliver a prescription order to any location requested by the patient. A pharmacy that delivers prescription orders by one or more alternate methods shall have policies and procedures to ensure patient confidentiality, prescription order accountability, and proper storage of prescription orders during delivery. When counseling is required pursuant to rule 657—6.14(155A), oral counseling shall be provided before the prescription order is delivered to the patient. Documentation of the delivery of prescription orders shall be maintained by the pharmacy for at least two years from the date of delivery. The term "patient" includes the patient and the patient's authorized representatives.

As such, pharmacies may implement procedures as allowed by the amended rule to provide prescription delivery services to patients as they request, ensuring patient confidentiality, accountability, and proper storage of the medication(s).

Question: Our pharmacy delivers filled prescriptions to patients who reside in assisted-living facilities. Some of those facilities have asked that deliveries be dropped off at a central location, staffed by a registered nurse or licensed practical nurse. Can we do that?

Answer: Yes. Under the Board's recently adopted amendment to 657 IAC 8.15 (see previous question for text of amended rule) for prescription delivery, the pharmacy can deliver a patient's prescription to any location of the patient's choice, as long as the pharmacy can ensure patient confidentiality, accountability, and proper storage of the medication(s).

Question: My local school nurse has student medications that need to be returned to students who cannot return to school to pick up their medication. Can my pharmacy receive these medications back?

Answer: Yes. If the patient or caregiver cannot get to the school to pick up their medication, the medication can be taken back to the pharmacy *which originally dispensed it* (either the nurse bringing it to the pharmacy or the pharmacy arranging to pick up the medication from the school). The pharmacy can then hold the medication in their will-call area for the patient to come pick up the medication or the pharmacy may deliver the medication to the patient/caregiver.

Question: Can my pharmacy set up a "curbside delivery" service, with patients being asked to drop off written prescriptions and pick up their filled prescriptions outside of the pharmacy building?

Answer: Yes. The pharmacy needs to ensure the adjusted procedures ensure patient confidentiality, accountability, and proper storage of medication(s). If a patient requires counseling and the counseling was not provided in advance of the patient picking up the medication (preferable), staff working the "curbside delivery" location must gather from the patient a phone number at which the patient may be contacted for the pharmacist to call to provide counseling.

PHARMACY PRACTICE (Prescription limitations, Patient Counseling, Substitution)

Question: We have a patient who is out of refills for a medication. We have been unable to get a response from the patient's prescriber. Can we refill the prescription without authorization?

Answer: Unless it's a controlled substance, yes. Iowa Code section 155A.29 currently authorizes pharmacists to exercise professional judgment by refilling a prescription one time without prescriber authorization *if all of the following are true*:

a. The pharmacist is unable to contact the prescriber after reasonable effort.
b. Failure to refill the prescription might result in an interruption of therapeutic regimen or create patient suffering.
c. The pharmacist informs the patient or the patient's representative at the time of dispensing, and the practitioner at the earliest convenience, that prescriber reauthorization is required.

Answer: If it's a controlled substance, federal regulation has not been amended or lifted, to date, to allow renewal of a controlled substance prescription without prescriber authorization.

Question: A patient has come to my pharmacy to get a prescription filled because the patient's regular pharmacy has closed indefinitely. My staff has also been unable to contact the prescriber due to their clinic being closed. Can I fill the prescription without getting the required transfer or new prescription from the prescriber?

Answer: Unless it's a controlled substance, yes. Iowa Code section 155A.29 currently authorizes pharmacists to exercise professional judgment by refilling a prescription one time without prescriber authorization *if all of the following are true*:

a. The pharmacist is unable to contact the prescriber after reasonable effort.
b. Failure to refill the prescription might result in an interruption of therapeutic regimen or create patient suffering.
c. The pharmacist informs the patient or the patient's representative at the time of dispensing, and the practitioner at the earliest convenience, that prescriber reauthorization is required.

Question: Can our pharmacy discontinue provision of face-to-face counseling?

Answer: Yes, as long as the pharmacy has some equivalent method to provide the needed information to the patient. Governor Kim Reynolds' March 17, 2020, State of Public Health Disaster Emergency includes provisions to expand patient interactions with health care practitioners via telecommunications. While the Board strongly believes that patient safety is best protected by a pharmacist counseling a patient about their medication *before* it is delivered or dispensed to a patient, the pharmacy can certainly adjust processes to conduct such counseling in an alternate manner, such as via telephone.

Question: Is a pharmacist authorized to engage in therapeutic interchange of a medication when or if the prescribed medication is not available, without contacting the prescribing physician for authorization?

Answer: Temporarily, yes, with strict conditions. Governor Reynolds' April 2 Proclamation of Disaster Emergency (extended in her July 24, 2020 Proclamation to be permitted through August 23) temporarily authorizes pharmacists to engage in therapeutic substitution pursuant to Guidance by the Board, issued April 6, 2020. Note that this authorization does NOT apply to controlled substances. The Iowa Pharmacy Association has developed this Therapeutic Substitution Flowchart to assist pharmacists in their decision-making process.

Question: How do I handle prescriptions which are subject to REMS laboratory testing?

Answer: Please review Coronavirus (COVID-19) Update: FDA provides update on patient access to certain REMS drugs during COVID-19 public health emergency for guidance.

Question: Should pharmacists continue to provide routine immunizations during the COVID-19 pandemic?

Answer: The CDC published a general answer to this question:

Q: Should any diagnostic or therapeutic interventions be withheld due to concerns about transmission of COVID-19?

A: Patients should receive any interventions they would normally receive as standard of care. Patients with suspected or confirmed COVID-19 should be asked to wear a surgical mask as soon as they are identified and be evaluated in a private room with the door closed. Healthcare personnel entering the room should use Standard and Transmission-based Precautions.

Continued influenza immunizations have the potential to result in fewer patients that have influenza symptoms that could be confused for those of COVID-19. This has the potential to reduce the number of patients seeking advice from the healthcare system, potentially requesting COVID-19 tests that will result as negative. This is equally true for other routine immunizations; anything that can contribute to fewer patient visits to prescriber offices and hospitals will allow those entities to triage patients with coronavirus exposure symptoms and care for those patients with advanced COVID-19.

The Board encourages pharmacists to continue to provide routine immunizations *if practitioners feel comfortable and those procedures can be performed according to the CDC Infection Prevention and Control Recommendations for Patients Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Setting Guidelines.*

Please pay attention to these details:

- Limit how germs enter your facility
    - If patients have respiratory symptoms, please direct them to their healthcare provider.
    - Only the patient receiving the immunization should be present with staff in the procedure room. Extra people should be minimized to the extent possible.
    - Ensure staff is familiar with recommended hand hygiene procedures; staff must perform these procedures before and after patient contact.
    - Ensure staff self-isolate if they have symptoms or have been exposed to people with COVID-19 symptoms. Staff that meet these criteria must not perform immunization procedures.
- Staff should wear required Personal Protective Equipment (PPE) since recommended physical distancing cannot be employed, which includes:
    - Gloves
    - Gowns
    - Respirator or mask
- Staff should disinfect the procedure areas immediately after finishing immunization administration.

Question: My pharmacy has been presented with a prescription issued by a practitioner who is not currently licensed in Iowa. Is this a legal prescription?

Answer: As long as the prescription meets all other requirements and was issued during the period of time identified in Governor Reynolds' March 22 Proclamation of Public Disaster Emergency (extended in the July 24 Proclamation through August 23), yes. Additional information is provided by the Iowa Board of Medicine, Iowa Dental Board, and the Iowa Board of Nursing. For the duration of the Disaster Emergency, the Board will not require an unlicensed prescriber who is

practicing pursuant to the appropriate professional licensing board parameters to hold an Iowa CSA prior to issuing a prescription for a controlled substance.

Question: Is the electronic prescribing mandate waived during this state of emergency?

Answer: The electronic prescribing mandate has not been specifically identified in any of the Governor's State of Public Health Disaster Emergency proclamations. Iowa Code provides a number of exemptions for the mandate, including an emergency. Under current Board rule, an emergency is defined as including, *but not being limited to*, issuing a prescription to meet the immediate care needs of a patient after hours when a prescriber may not have access to their electronic prescribing system. During this current COVID-19 pandemic, workflow and operational practices may become untenable which may lead to lack of access to these prescribing systems or other significant barriers. In keeping with the current exemption for emergency situations, a practitioner may transmit a prescription via other than electronic methods in a situation that they deem is an emergency, including when they may not be able to access their electronic prescribing system. Prescribers are encouraged to seek additional guidance from their professional licensing board as those boards are tasked with enforcement of the mandate.

Question: Did Governor Kim Reynolds suspend the rules relating to procedures for authentication of verbal orders and standing orders?

Answer: Temporarily, yes. In Governor Reynolds' April 10 Proclamation of Disaster Emergency, Section 13 (and extended in her July 24 Proclamation to continue through August 23), she temporarily suspended the regulatory provisions of the Department of Inspections and Appeals' rules requiring procedures for authentication of verbal orders and standing orders, to the extent that hospitals comply with federal regulation related to such orders.

CONTROLLED SUBSTANCES

Question: Is my pharmacy allowed to skip the signature requirement for over-the-counter sales of pseudoephedrine or over-the-counter dispensing of schedule V cough syrups?

Answer: At this time, no. The Board is not intending to exercise enforcement discretion relating to any rule which applies to controlled substances. Further, DEA Guidance relating to the signature requirement for pseudoephedrine logbooks continues to require the signature of the purchaser.

Question: I heard the DEA has relaxed some of the regulations on phoned-in emergency CII prescriptions?

Answer: Yes, on March 27, 2020, the DEA published Guidance relating to oral emergency CII prescriptions which provides temporary exemptions to two required components of an oral emergency CII prescription. The Guidance allows prescribers to 1) submit the follow-up prescription to the pharmacy within 15 days (current regulation requires 7 days) and 2) submit the follow-up prescription via alternate methods, such as via facsimile or by a photograph or scan of the prescription sent to the pharmacy. Note that emergency prescriptions still must be transmitted

directly from the prescriber to a pharmacist and that the follow-up prescription must still include all the required elements, including the notation "Authorization for Emergency Dispensing." Pharmacists are encouraged to solicit the intended method of submission for the follow-up prescription from the prescriber during the initial phone call and document the relevant information for subsequent verification (e.g., ask the prescriber to identify how the follow-up prescription will be submitted and document the fax number or email address from which the prescription will be provided for subsequent verification).

Question: If my facility or pharmacy has to temporarily relocate or expand to an alternate location due to coronavirus exposure or to expand patient capacity, how do we obtain a new CSA registration?

Answer: A facility or pharmacy that needs to temporarily relocate or expand facilities to respond to a coronavirus exposure or increase in patient needs, the board will exercise enforcement discretion as it relates to CSA registration when the facility/pharmacy follows these steps:
1) obtain a Department of Inspections and Appeals Health Care Waiver for CMS or State-Only Facilities (this requirement does not apply to pharmacies),
2) obtain a temporary registration from DEA to handle controlled substances at the temporary location, and
3) notify Board staff of the situation.

Question: I heard that the DEA has temporarily paused its regulation which limits distribution of controlled substances to another registrant to 5% of the registrant's annual dispensing/distribution?

Answer: Yes, due to the COVID-19 pandemic and the challenges posed, DEA has issued this Letter to DEA Practitioners on April 13, 2020 in which it grants a temporary exception to 21 CFR 1307.11. If a registrant is compliant with all other aspects of distribution (such as security, recordkeeping, etc.), the DEA will not limit a registrant's distribution to 5% of its annual dispensing/distribution. The temporary authorization is backdated to January 1 and extends through the end of the national disaster emergency declaration. Upon the expiration of the national disaster emergency, the registrant will only have to count any distribution from that point through the end of the calendar year in its annual distribution calculation. Pharmacies should note that any distribution of prescription drug products, including controlled substances, are subject to the federal drug supply chain security act conditions, unless the distribution is an exempted transaction (such as to meet a specific patient need or in response to a public health emergency).

Question: I heard that the DEA has temporarily authorized DEA-registered hospitals and clinics to have controlled substances delivered to and handled by a satellite hospital/clinic which is not DEA-registered?

Answer: Yes, under very specific parameters, DEA will allow a DEA-registered hospital/clinic, under its existing DEA registration, to handle controlled substances at a satellite hospital/clinic location (one or more). The parameters include, but are not limited to, the satellite hospital/clinic was set up to provide temporary services connected to the public health emergency resulting from

the COVID-19 pandemic, certain records are maintained, and that physical security and effective controls against diversion are maintained. Hospitals or clinics which may be subject to the DEA allowance must review and maintain compliance with the DEA Letter to Hospitals/Clinics, Manufacturers, and Distributors (April 10, 2020).

Question: Can registered pharmacies postpone DEA biennial controlled substance inventories during the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 (COVID-19)?

Answer: No. A biennial inventory is required under the Controlled Substances Act (CSA) as enacted by Congress. **21 U.S.C. 827**(a)(1) requires that "every registrant under [Subchapter I-Control and Enforcement] shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply." As such, the statutory text of the CSA requires registrants engaged in the manufacture, distribution, and dispensing of controlled substances to conduct an inventory no less often than biennially. DEA's regulations implementing this provision permit such registrants to conduct the inventory "on any date which is within two years of the previous biennial inventory date," but the regulations, like the statute, do not permit the inventory to be delayed beyond two years. **21 CFR 1304.11**. No waiver or exemption is currently in effect to excuse general compliance with this requirement for dispensers, including pharmacies. Any questions about the applicability of these requirements to a registrant's particular situation should be directed to the Diversion Control Division Policy Section at (571) 362-3260.

REMOTE PROCESSING

Question: Will the Board allow pharmacists and technicians to work remotely from home in order to complete duties that would normally have to occur within a licensed pharmacy?

Answer: Yes. The pharmacy needs to be able to ensure confidentiality of patient files at the remote location, security of the computer system and internet connection (preferably encrypted), and that all work performed by a technician is reviewed by a pharmacist. As it relates to tasks involving product verification, the computer hardware and software must be adequate for the task being performed, such as using two-way, real-time audiovisual connection (not just audio connection).

Question: Can pharmacists and technicians working in a pharmacy be remotely involved in the dispensing process of another pharmacy?

Answer: Yes, as long as the pharmacies involved have the appropriate hardware and software to exchange the necessary data to safely and securely perform the tasks and that work completed

by technicians that would otherwise be verified by a pharmacist continues to be verified by a pharmacist.

PHARMACY SERVICES FOR LONG-TERM CARE FACILITIES

Question: Can our pharmacy delegate stocking an automated dispensing machine used for emergency doses to a facility nurse if the facility has restricted access to the facility?

Answer: Yes, if the automated dispensing machine has barcode-scanning capability.

PHARMACIST-TECHNICIAN / PHARMACIST-INTERN RATIOS

Question: Will the Board allow pharmacies to exceed the pharmacist-technician ratio (in technician product verification programs) or pharmacist-pharmacist intern ratio?

Answer: Yes, but only if the purpose in doing so is necessary due to an actual impact of the COVID-19 virus on the pharmacy, facility, or staff involved. Pharmacists should continue to be diligent in their supervision of pharmacist-interns to ensure proper information is provided to patients and accurate work is being completed.

CONTINUING EDUCATION / TRAINING

Question: My CPR certification is due to expire soon and the training organization has indefinitely suspended all in-person training. Will I have to discontinue administering immunizations until I can complete certification?

Answer: No. The Board recognizes that many in-person events have been cancelled or postponed indefinitely and believes that the public safety is still best protected in ensuring access to vaccinations. If there are other immunizing personnel in the pharmacy available to administer vaccinations, have those individuals perform that task. If you are the only immunizer available, you are encouraged to complete an online, didactic program to at least receive refresher information, but it will not be viewed as an acceptable substitute for the hands-on training obtained during a CPR certification program for healthcare providers. The Board will exercise enforcement discretion for those pharmacists who are unable to renew CPR certification during this emergency situation.

Question: The Governor's March 22 Proclamation relaxes the continuing education requirements for license renewal. Will this apply to my pharmacist license renewal this year?

Answer: On March 27, the Board issued its Response to the Governor's Proclamation which addresses this issue. On April 27, 2020, Governor Reynolds signed a new Proclamation of Disaster Emergency which extends the regulatory relief through May 27, 2020 (which was continued again in her July 24 Proclamation to extend through August 23). Legislative action was

taken during the 2020 session (HF 2627) which extends the due date for all 2020 continuing education requirements to be completed by June 30, 2021.

Question: Did the Governor relax the mandatory reporter training requirements during this emergency period?

Answer: Yes. In Governor Reynolds' April 10 Proclamation of Disaster Emergency, Section 30 (which was extended through August 23 in her July 14 Proclamation), she temporarily suspends the requirement that mandatory reporter training be completed within six months of initial employment for those that qualify as a mandatory reporter. The regulatory pause does not extend to the required reporting of a case of child or dependent adult abuse to the proper authorities.

PHARMACIST-INTERN / PHARMACIST LICENSURE CANDIDATE ISSUES

Question: The Governor's March 22 Proclamation relaxes the rules relating to the completion of clinical, practical, or internship experience for licensure. How long will that be in effect?

Answer: The Governor's Proclamations are valid between March 22 and August 23, 2020. Iowa-licensed pharmacist-interns who are currently completing or who are scheduled to complete their experiential program to qualify for graduation this spring (2020) and are unable to complete the college-based clinical program, due solely to the COVID-19 pandemic, will continue to be eligible for pharmacist licensure in Iowa if all other requirements are met. On March 27, the Board issued its Response to the Governor's Proclamation which provides more information. The Board will continue to monitor the situation for pharmacist-interns who are beginning their experiential program for spring 2021 graduation.

Question: The Governor's March 22 Proclamation relaxes the rules relating to the completion of background checks for professional licensure. How long will that be in effect?

Answer: The Governor's Proclamations are effective between March 22 and August 23. On March 27, the Board issued its Response to the Governor's Proclamation which provides more information. The Board issued an updated Response following the May 26 Proclamation. The Board will continue to handle deferred background checks as identified in previous responses as the Proclamations are extended or terminated.

Question: I'm a pharmacist licensure applicant and have successfully completed one of the two required exams to qualify for licensure, but the testing centers have closed and I cannot take the second exam at this time. Will I lose credit for the first exam I have taken if I reach/exceed the one year requirement for passing both components?

Answer: No, you will not lose credit. The Governor's March 22 Proclamation relaxes the rule which requires both exam components to be completed within one year of passing the first exam (authorization which was extended through August 23 in the Governor's July 24 Proclamation). On March 27, the Board issued its Response to the Governor's Proclamation which provides more information. The Board issued an updated Response following the May 26 Proclamation. The

Board will continue to handle these situations as identified in prior responses as Proclamations are extended or terminated.

Question: What is the status of the Pearson Vue testing locations?

Answer: The Board has been made aware that Pearson Vue has reopened select testing locations across the country for limited testing, implementing significant measures to prevent spread of the coronavirus. Three locations are open in Iowa (western, eastern, and central Iowa). Pearson Vue has included pharmacist licensure candidates in their top tier of priority testing. When a pharmacist licensure candidate receives their authorization to test from NABP, the authorization will include a list of available testing sites. Pearson Vue has indicated that special accommodations (such as extended testing time) cannot be granted at this time. Pearson Vue has indicated that anyone who had previously received an authorization to test should be able to reschedule their exam, which will provide available testing locations at which the exam may be taken. Note that Pearson Vue is still operating testing centers with significant procedures to prevent transmission of the coronavirus. The Board will continue to monitor the situation and provide updated information as it is available.

Question: What is the process for a newly graduated pharmacist-intern to obtain emergency licensure under the Governor's Proclamation of Disaster Emergency?

Answer: In her April 27 Proclamation of Disaster Emergency, Section Eighty-Four (and extended in subsequent Proclamations, currently through August 23), Governor Reynolds authorized the Board to issue emergency pharmacist licenses to candidates who have, as determined by the Board, completed sufficient education, are unable to sit for required examinations due to closure of testing locations, and should be granted an emergency license to practice until such time as the licensee is able to complete the required examinations. The specific guidance which details the implementation of the issuance of emergency licenses can be found on the Board's COVID-19 Information and Updates web page.

PHARMACY PERSONNEL / LICENSING ISSUES

Question: Can I continue to have a technician trainee working in the pharmacy if their trainee registration is due to expire soon but their CPhT national exam has been postponed due to COVID-19?

Answer: Yes. The Governor's Proclamations temporarily suspended the rule which would prohibit a technician trainee from practicing as a technician following the expiration of the trainee's one-year registration unless the technician has obtained national certification. The Proclamation allows a technician trainee whose registration expires between March 22 and July 31, and who is unable to sit for the examination, to continue to practice as a technician while the registration is expired. The Board will continue to monitor the situation with testing sites and will exercise enforcement discretion if necessary following the expiration of the Governor's waiver. PTCB recently issued a press release which announced that the national technician certification exam

will be available via online proctoring. Technicians are encouraged to visit PTCB's Testing During COVID-19 information page for more information.

Question: What if pharmacy personnel have no child-care options? Can pharmacy personnel bring their child(ren) into the pharmacy while they work?

Answer: The Board certainly understands this could become a reality as schools have been closed across the state. The Board would be inclined to exercise enforcement discretion if the pharmacy can ensure patient confidentiality, security from unauthorized access to prescription drugs (including and especially controlled substances), and general quality patient care.

Question: If my pharmacy needs to hire new pharmacy technicians and pharmacy support persons which are intended to be temporary positions to get through the emergency period, do we still need to register them with the Board?

Answer: The Board's existing rule is to obtain registration within 30 days of employment. Although the Board office is closed to public visitors, Board staff is currently continuing regular operations. Applications may be submitted via regular mail or brought to the Board office and deposited into the drop box in the front vestibule. Licensing staff will continue to process applications as normal and the Board will exercise enforcement discretion in situations where the application has been received but not processed within the required timeframe. Keep in mind that some tasks that may be ramped up during this time do not require registration with the Board, such as delivery.

Question: Can the pharmacy utilize store employees who are not currently registered with the Board in any capacity to assist with duties normally handled by registered pharmacy support persons, such as entering the pharmacy to assist with handling payment transactions for prescriptions?

Answer: During this emergency period, the Board will exercise enforcement discretion in situations where, expressly due to personnel impacts resulting from COVID-19, a pharmacy allows an unregistered employee to assist with pharmacy support person tasks.

Question: My pharmacy has experienced an unexpected loss of technician staff. Can my registered pharmacy support person(s) engage in technician duties to assist the pharmacist?

Answer: Yes. During this emergency period, if your pharmacy can demonstrate that there has been an unanticipated change in staffing due to the COVID-19 outbreak, and you are unable to hire additional technician staff, you may initiate training of pharmacy support staff to engage in technician duties to assist pharmacist staff with prescription dispensing activities during the emergency period. The Board's current rules provide that a pharmacy has 30 days in which to obtain registration for a new registration type for an employee, and the Board's enforcement discretion would cover this situation. If, at the end of the emergency period, the pharmacy determines that the employee would continue with technician duties as a technician trainee, the pharmacy will need to ensure that the employee obtains appropriate registration.

Question: Can a pharmacist that is licensed and in good standing in another state perform work inside Iowa or remotely from another state?

Answer (non-IA-licensed RPh working in out-of-state pharmacy): Pharmacists who work in an Iowa-licensed non-resident pharmacy may provide pharmacist services for Iowa patients without specifically holding an Iowa pharmacist license.
Answer (non-IA-licensed RPh working in Iowa pharmacy): Governor Reynolds' March 22 Proclamation allows an Iowa pharmacist whose license is inactive or lapsed (for no more than 5 years) to return to the practice of pharmacy through the emergency period (March 22 through August 23, as extended in the Governor's July 24 Proclamation). On March 27, the Board issued its Response to the Governor's Proclamation. The allowance does not extend to pharmacist licenses which were voluntarily surrendered or revoked. In Governor Reynolds' April 2 Proclamation of Disaster Emergency (extended in subsequent Proclamations to be effective through August 23), the regulatory provision of Iowa Code section 155A.7 was temporarily suspended to allow a pharmacist who is licensed in another state to practice pharmacy in Iowa, pursuant to Guidance by the Board, issued April 6, 2020.

Question: The Governor's March 22 Proclamation relaxes the rules relating to license and registration renewals. How long will that be effective and can I still practice if I haven't renewed my license or registration?

Answer: *The suspension applies to licenses and registrations which expire between March 22 and August 23 only*. The Board of Pharmacy is operational at this time and licensing staff is continuing to process license and registration renewals. The Board has no expectation at this time that applications will not be processed as normal. Licensees and registrants are encouraged to utilize the Board's online renewal process. Licensees and registrants who are unable to renew and whose license or registration expires between March 22 and August 23 are authorized to continue practice until they are able to submit for renewal. On March 27, the Board issued its Response to the Governor's Proclamation which provides more information. The Board issued this additional Guidance in response to the Governor's April 2 Proclamation. The Board's online renewal system has been updated to pause the late penalty fee for the renewal of licenses/registrations which expired between March 31 and July 31. If your license/registration is subject to the Governor's Proclamations, you will not owe a late penalty fee for your renewal if it was submitted within 30 days of the expiration of the Proclamation. If your license/registration is subject to the Proclamation exemption and you were assessed a late penalty fee via online renewal, please contact the appropriate Licensing Clerk for a refund.

Question: I've heard that a pharmacist whose license has expired would be able to come back to work during this pandemic. Is that true?

Answer: Yes, with some conditions. The Governor's March 22 Proclamation relaxes the rules which would otherwise prohibit a pharmacist from practicing with an expired or lapsed license (authorization which was extended through August 23 in the Governor's July 24 Proclamation). A pharmacist whose license has been inactive or lapsed for less than 5 years may return to work as a pharmacist in Iowa. The Governor's action does not appear to apply to pharmacists whose

license has been voluntarily surrendered or revoked. Pharmacists and pharmacies are not required to report to the Board the utilization of this aspect of the Governor's Proclamation. Pharmacists working in a pharmacy on a temporary basis during this emergency period shall sign the pharmacy's intermittent log each day and shift worked.

Question: A member of my staff is believed to be infected with COVID-19. When can they return to work?

Answer: Refer to current CDC Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19 (Interim Guidance) (March 16, 2020).

Question: What are the recommendations for pharmacy personnel who believe they have been exposed to coronavirus?

Answer: Refer to IDPH Isolation Guidance for Essential Services Personnel (March 22, 2020).

Question: Is the Board waiving licensure requirements for manufacturers to ship COVID-19 point-of-care test kits into Iowa?

Answer: The Board has not relaxed licensure requirements for entities part of the drug supply chain, as part of the Board's mission to protect the health, safety and welfare of Iowans. That said, a manufacturer which does not qualify as a wholesale distributor under federal law would be covered under the Board's Limited Distributor Licensure requirements. If the distribution is limited to "distribution of medical devices exclusively to a health care practitioner for use in the normal course of professional practice ("professional use")", licensure is optional.

Question: Can my pharmacy or hospital order COVID-19 testing kits from a wholesale distributor that is not licensed in Iowa?

Answer: If the wholesaler's distribution into Iowa is limited to medical devices (such as COVID testing kits) to a health care practitioner for use in the normal course of professional practice ("professional use"), yes. This distribution activity is covered under the Board's "optional licensure" with a Limited Distributor License. The wholesaler would not be authorized to distribute any prescription drug product (such as albuterol inhalers, etc.) without prior licensing as a wholesale distributor in Iowa.

PHARMACIST SCOPE OF PRACTICE and PROTOCOLS

Question: Will the Board be temporarily expanding the scope of practice for pharmacists so that they can perform functions like conducting COVID-19 or rapid strep tests *with subsequent prescribing of appropriate antibiotics*?

Answer: Not at this time. The authority to allow pharmacists to engage in such testing *with subsequent prescribing* comes solely from the Iowa Legislature. Under existing law, pharmacists are authorized to practice under a collaborative practice agreement with a practitioner to engage in patient care activities. Under Board rules, the collaborative practice agreement would typically

only apply to patients of the practitioner who has authorized the agreement. The Board would take enforcement discretion in situations where a practitioner has authorized any pharmacist subject to the collaborative practice agreement to engage in the authorized pharmacist services for patients other than the authorizing practitioner.

Question: If a vaccine is approved by FDA and available for administration to prevent the novel coronavirus, will pharmacists be authorized to administer the vaccine under a physician-signed immunization protocol or the Board's statewide protocol?

Answer: Yes. When a vaccine is approved by FDA and added to the ACIP recommendation guidelines, a pharmacist is authorized to administer the vaccine to a patient pursuant to the Board's statewide protocol for immunizations. Under the Board's statewide protocol, a pharmacist is authorized to administer to patient's six months of age and older "other immunizations in response to a public health emergency." If the state's public health emergency has expired or been lifted at the time a vaccine becomes eligible for administration, a pharmacist would only be authorized to administer the vaccine to patients aged 18 or older.

The Iowa Code provision which authorizes immunization administration by pharmacists under a physician-signed protocol was set to sunset on June 30, 2020, but the Iowa Legislature postponed the sunset until June 30, 2021. If a vaccine is eligible for administration prior to June 30, 2021, the physician-signed protocol would need to be updated to reflect the vaccine authorization.

Question: Can my pharmacy conduct COVID-19 diagnostic and/or serologic tests? (Updated August 17, 2020)

Answer: Yes. The PREP Act and subsequent HHS Guidance authorize pharmacists to order and administer COVID testing, including serology tests, authorized by FDA. This authority provides pharmacists with the independent authority to order and administer a test without a specific order from a prescriber to do so. This authority extends only through the federal government's designation of the public health disaster. Pharmacist administration of COVID testing beyond the federal public health disaster must be pursuant to an order by a licensed healthcare practitioner authorized to prescribe.

Types of tests which can be ordered and administered by pharmacists

The HHS Guidance authorizes pharmacists to order and administer COVID tests *which are authorized by FDA*. The pharmacist must ensure that the test to be administered is authorized by FDA either under a normal approval process or through the FDA's Emergency Use Authorization process. *Pharmacists are not authorized to order and administer a COVID-19 test which has not received FDA authorization, even if it may be available in the marketplace.*

- *Diagnostic COVID-19 Testing at the Point-of-Care / Patient Care Setting (Pharmacy)*

As of August 17, there are four molecular diagnostic tests authorized by FDA to be used at the point-of-care: Abbott ID NOW, GeneXpert Xpert Xpress, Accula, and Cue. Information about the use of the Abbott ID NOW can be found HERE.

As of August 17, there are two antigen diagnostic tests authorized by FDA to be used at the point-of-care: Quidel's Sofia 2 SARS which utilizes a nasal or nasopharyngeal swab and BD Veritor System which utilizes a nasal swab.

- *Diagnostic COVID-19 Testing at Laboratory with Specimen Collection at Pharmacy*

There are currently many diagnostic tests authorized by FDA to be processed by a moderate or high-complexity CLIA laboratory. The pharmacy would collect the patient's respiratory specimen at the pharmacy (the type of respiratory specimen collected would be determined by the test kit to be used and could include a simple nasal swab or more invasive nasopharyngeal swab) and send the specimen to a moderate or high-complexity laboratory for testing (the complexity of the lab would be determined by the test kit to be used).

- *Diagnostic COVID-19 Testing at Laboratory with Specimen Collection at Patient's Home*

As of August 17, there are several diagnostic tests authorized by FDA which authorize at-home specimen collection. The FDA website for EUAs includes the tests which are authorized for at-home specimen collection. The companies appear to provide direct patient access to go through the company directly to obtain the test kit.

- *Serologic COVID-19 Testing at the Point-of-Care / Patient Care Setting (Pharmacy)*

There are currently no COVID-19 serology tests authorized by FDA to be used at the point-of-care in a location with a CLIA Certificate of Waiver. It should be noted that, even when a serology test may be authorized by FDA for POC use, the Iowa Department of Public Health cautions against using tests that simply require a finger stick specimen in the absence of rigorous testing to ensure the tests are accurate and reliable in their results.

- *Serologic COVID-19 Testing at Laboratory with Specimen Collection at Pharmacy*

There are currently several COVID-19 serology tests authorized by FDA to be processed by a moderate- or high-complexity CLIA laboratory. Unless the pharmacy has attained a CLIA Certificate of Compliance, the pharmacy would collect the patient's blood specimen at the pharmacy (the type of blood specimen collected would be determined by the test kit to be used, likely a venipuncture sample) and send the specimen to a moderate- or high-complexity laboratory for testing (the complexity of the lab would be determined by the test kit to be used). It should be noted that the Iowa Department of Public Health cautions against using tests that simply require a finger stick specimen in the absence of rigorous testing to ensure the tests are accurate and reliable in their results.

Delegation of tasks to technicians

As pharmacists consider engaging in any type of COVID-19 testing, they should continue to comply with laws and rules relating to pharmacist responsibilities for dispensing, delegation of tasks, and supervision of pharmacy personnel. Pharmacists are authorized to independently order and administer COVID-19 tests, and to dispense a test ordered by another provider, including another pharmacist. Pharmacists may delegate appropriate non-clinically judgemental tasks associated with testing to pharmacy personnel who are appropriately trained and working under pharmacist supervision.

Laboratory information

- *Point-of-care testing (POCT)*: If a pharmacy intends to order and administer POCT, it must first have a current CLIA Certificate of Waiver to conduct CLIA-waived tests, such as POCT for COVID-19. A pharmacy that does not have a CLIA Certificate of Waiver may complete the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS Form 116) and submit to the:

  Iowa CLIA Laboratory Program
  State Hygienic Laboratory
  University of Iowa Research Park
  2490 Crosspark Road
  Coralville, IA 52241
  (319) 335-4500 or (800) 421-IOWA
  FAX: (319) 335-4174
  Email: shl.clia@uiowa.edu

  On the application for a CLIA Certificate of Waiver, the pharmacy may be required to identify the specific CLIA-waived test(s) intended to be administered at the pharmacy.

- *Moderate- or High-Complexity testing*: Pharmacy collection of patient specimens (respiratory for diagnostic, venous blood for serologic) for subsequent moderate- or high-complexity lab analysis must identify and coordinate with a laboratory for such testing. No CLIA Certificate of Compliance or Waiver is required for specimen collection. Possible laboratory options may include, but cannot be guaranteed by the Board:
    - Quest Diagnostics
    - ARUP
    - LabCorp
    - State Hygienic Lab

Policies and Procedures

The pharmacy must ensure that, depending on the test(s) to be conducted, a complete policy and procedure is established and followed which includes but is not limited to:

- Notification of the pharmacy's intent to order and administer COVID-19 tests via updating the pharmacy's online profile with the Board via View User Profile and Update Demographics to identify "COVID-19 Diagnostic" or "COVID-19 Antibody" testing as an available pharmacy service;
- Notification to the test kit manufacturer and FDA (via email at CDRH-EUA-Reporting@fda.hhs.gov) of any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test kit;
- Patient screening parameters prior to ordering and administering a test, including identification of testing priority groups;
- Personnel training required prior to engaging in specimen collection and testing, including review and understanding of the test kit manufacturer instructions / package insert;
- Strict adherence to the testing procedure identified in the test kit manufacturer instructions / package insert;
- Appropriate use of personal protective equipment (PPE);
- Environmental security measures that will be in place to prevent the spread or transmission of the coronavirus by a potentially infected individual presenting to the testing site;
- Evaluation of test results;
- Dissemination of test results to the patient, the patient's primary care practitioner, and the local public health agency; and
- Patient guidance to be provided based on the test type (diagnostic or serologic) and test result (positive or negative).

Personnel Training

Pharmacy personnel who will be conducting COVID-19 testing must be properly trained on the testing policy and procedures, proper specimen collection, proper use of personal protective equipment (PPE), and evaluation of test results prior to engaging in specimen collection and/or testing. Documentation of completed training, and documented observed competency for specimen collection and use of PPE, for each individual involved in specimen collection and/or testing must be maintained in the pharmacy and available for inspection and copying by the Board or its authorized representative.

Supplies for Collection of Patient Specimens

A pharmacy engaged in COVID-19 testing, either at POC or collection of specimens for moderate- or high-complexity laboratory testing, which is having difficulty obtaining supplies for collecting patient specimens should review the FDA website Contacts for Medical Devices During the COVID-19 Pandemic for more information.

Test Result Reporting

A pharmacy engaged in ordering or analyzing COVID-19 tests (including at POC, collection of specimens for moderate- or high-complexity laboratory testing, or ordering a test for a patient's at-home specimen collection and submission to a moderate or high-complexity laboratory) must provide all test results to the patient, the patient's primary care practitioner (if identified), and to the Iowa Department of Public Health (electronically through the Iowa Disease Surveillance System, preferred, or via fax to 515-281-5698). If the pharmacy is only involved with overseeing specimen collection but is not the ordering practitioner or lab conducting the test analysis, the pharmacy is not required to report test results.

The pharmacy, regardless of the pharmacy's level of involvement in testing, must update the pharmacy's online profile with the Board via View User Profile and Update Demographics to identify the pharmacy's service(s) of "COVID-19 Diagnostic" and/or "COVID-19 Antibody" testing. Within approximately 48 hours, the pharmacy will receive via email a template to use for submission of test results to the IDSS, if the pharmacy is required to report based on the pharmacy's level of involvement in testing. If the pharmacy has not received the template within 72 hours, please contact sue.mears@iowa.gov.

Mandatory reporting of all COVID-19 test results is pursuant to an order issued April 18, 2020 by Dr. Caitlin Pedati, IDPH Medical Director and State Epidemiologist, and extends through December 31, 2020.

Treatment Following a Positive COVID-19 Test Result

Under current Iowa law, a pharmacist is not authorized to order and dispense any prescription medication in response to a positive diagnostic test for COVID-19 (or any other point-of-care test). A patient whose diagnostic test result is positive (or whose serologic IgM test result is positive) must be referred to a prescriber for further evaluation and possible treatment.

Billing to CMS

The US Centers for Medicare & Medicaid Services (CMS) recently published information allowing pharmacies to temporarily enroll as an independent clinical diagnostic laboratory for the purpose of reimbursement for COVID-19 testing. Note that the information and subsequent enrollment does not impact or override the CLIA requirements for laboratories. Pharmacies would still be limited to conducting tests that are authorized for their level of CLIA certification.

On July 31, 2020, CMS and CDC announced that provider reimbursement is available for counseling patients to self-isolate at the time of the COVID testing. Providers who are eligible to bill CMS for counseling services will be able to use existing evaluation and management (E/M) payment codes for reimbursement. Further information and resource links are available in the Counseling Check List PDF.

Final Reminder

The information provided here is current as of August 17, 2020. A pharmacy engaged in COVID-19 testing must continue to be aware of current recommendations and authorizations for such testing. While the HHS Guidance issued April 8, 2020 provides pharmacists immunity from damages as a result of conducting COVID-19 countermeasures, the Board's expectation is that pharmacists are conducting these tests under strict policy and procedures and adhering to the test kit product insert.

Question: When FDA authorizes a COVID-19 test for point-of-care use, does that mean it is CLIA-waived?

Answer: Yes. When the FDA issues a Letter of Authorization to a company to authorize a COVID-19 test under an Emergency Use Authorization, the letter will include the settings in which the EUA-authorized test may be performed. When FDA authorizes point-of-care tests (including for SARS-CoV-2) under an EUA, such tests are deemed to be CLIA-waived and can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver.

Question: Would my pharmacy be authorized to perform CLIA-waived COVID-19 testing at off-site locations?

Answer: Yes. Information provided in How to Obtain a CLIA Certificate of Waiver information, CLIA-waived tests can be provided at temporary locations.

Question: I am finding a lot of COVID-19 antibody (serology) tests available online for health care professionals to order. Can my pharmacy administer these antibody tests?

Answer: As of August 17, 2020, there are several COVID-19 antibody tests authorized for use by FDA under an Emergency Use Authorization ("EUA"), all of which are only authorized for use in a moderate or high-complexity laboratory. There are currently no COVID-19 antibody tests authorized under an EUA for use in a CLIA-waived laboratory, such as a pharmacy. FDA has relaxed its regulatory framework for development of these tests, allowing companies to develop and market test kits prior to receiving official approval from FDA. The companies are required to validate their test results prior to marketing their tests and are required to notify the FDA of their validation and intent to distribute. However, until a test kit has been authorized by FDA (either under the regular approval process or via an EUA), such test kit has not been assigned a CLIA designation. As such, *test kits which do not have FDA approval or FDA EUA are deemed to be conducted only in a high-complexity laboratory environment and, therefore, not approved for use at the point of care or patient care setting, such as in a pharmacy*.

Question: What is TestIowa.com?

Answer: TestIowa.com is an initiative by the State of Iowa to increase the rate of COVID-19 testing to expand access to testing and help stem the spread of the coronavirus. Iowans are encouraged to visit TestIowa.com and complete the assessment. Depending on the data provided, the individual will be notified if they are eligible to be tested for COVID-19 at one of the state's testing locations.

HOARDING OF DRUGS / SUPPLY CHAIN ISSUES

Question: Are we authorized to limit sales of over-the-counter medications and supplies, such as acetaminophen, ibuprofen, cough medicine, etc.?

Answer: Yes. The Board has no mandate that the pharmacy sell these products, so it is entirely a business decision for the pharmacy to set purchase limitations if desired.

Question: Can I dispense more than the authorized quantity of a prescription, if refills are available?

Answer: Unless it is a controlled substance, yes. Iowa Code section 155A.27, subsection 6, authorizes a pharmacist to dispense "up to the total number of dosage units authorized by the prescriber on the original prescription and any refills of the prescription, not to exceed a 90-day supply." It is recommended, however, that pharmacists exercise professional judgment in making determinations on dispensing additional quantities of prescription drugs. While it is beneficial to limit the number of pharmacy visits for patients, there is also a concern about adding to the strain of the drug supply chain.

Question: Am I authorized to limit a quantity dispensed on a prescription if I am concerned about drug supply chain issues?

Answer: Yes, you can use your professional judgment to dispense partial quantities of prescription medications in order to prevent the situation of limited drug supplies.

Question: How should my pharmacy handle prescriptions being issued for large quantities of hydroxychloroquine or chloroquine?

Answer: The Board encourages you to use your best professional judgment in determining the legitimacy of these prescriptions and the likely intent. For an example of what action other states are taking: the Idaho Board of Pharmacy issued an emergency rule that limits new prescriptions to a quantity of a 14 day supply along with a diagnosis code or documented positive COVID-19 test, unless the patient was previously established on the drug.

Question: How should my pharmacy handle requests from practitioners who want my pharmacy to distribute stock supplies of chloroquine, hydroxychloroquine, or other prescription drugs anecdotally identified as potential treatment or prophylaxis for COVID-19 for their "office use"?

Answer: Pharmacies are strongly encouraged to limit distribution of these products to only another pharmacy to meet a specific patient need (legitimate prescription for appropriate diagnosis).

Question: If my pharmacy has a drug in stock that is nearing expiration or recently expired, and it is the only product I have available to dispense, can I use it?

Answer: FDA has published information relating to Expiration Dating Extension and also publishes a list of drugs and devices subject to Emergency Use Authorization.

- Review FDA's Search List of Extended Use Dates to Assist with Drug Shortages to see if the product has been issued extended expiry by FDA. It is updated daily with information obtained from manufacturers. To request extended expiry for a drug, send an email to DRUGSHORTAGES@fda.hhs.gov, including detailed information of product(s) for the extended expiration request (NDC number, lot numbers, expiration dates, at a minimum).
- If the drug product is not approved for extended expiration and is a drug relevant to the current pandemic (such as ventilator drugs), the pharmacy may reach out to their Local Homeland Security and Emergency Management Coordinator to request supply from state resources. If the state does not have resources available, the state will elevate the request to their federal resources.

Question: My hospital is unable to procure certain drugs needed for our hospitalized COVID-19 patients which aren't showing on the FDA drug shortage list. Can we obtain these drugs from an outsourcing facility?

Answer: Yes, under very specific conditions and parameters. On April 16, 2020, FDA issued this Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency which identifies specific drug products which will be allowed to be compounded by outsourcing facilities for hospitalized COVID-19 patients. Facilities compounding the identified drugs must adhere to the specific conditions identified in the Policy in order to be eligible for the FDA's enforcement discretion policy. On May 8, FDA published this updated Temporary Policy which adds two drugs to the list of drugs authorized under the temporary policy. The FDA updated the Temporary Policy once again on May 21, 2020. The current list of drugs which may be compounded pursuant to the FDA's Temporary Policy can be found HERE.

Question: A compounding pharmacy called my hospital to offer compounded drug products that are in short supply without a patient-specific prescription. Can my hospital use this source of drug products?

Answer: Maybe, but use extreme caution. The FDA published a Temporary Policy (Updated May 8 and again May 21) which allows compounding pharmacies which are not registered as 503B outsourcing facilities to compound certain drug products for hospitals which are treating COVID-19 patients without first obtaining a patient-specific prescription, as would normally be required under the FD&C Act. Your pharmacy must exhaust all other sources of FDA-approved products before obtaining compounded products under this temporary policy (including checking FDA's searchable list of extended expiration dates; obtaining product from other Iowa-licensed dispensers, Iowa-licensed distributors, etc; and obtaining compounded products from Iowa-licensed outsourcing facilities). The hospital must ensure the compounding pharmacy is licensed in Iowa and should ensure the compounding pharmacy has obtained notification from the Board that it does not object to the compounding pharmacy's provision of the compounded drug product(s). The Board would ask that hospitals which obtain drug product(s) in this manner notify the Board with any product issues or adverse events associated with the drug product(s) provided under this temporary policy. The current list of drugs which may be compounded pursuant to the FDA's Temporary Policy can be found HERE.

These conditions must be met in order to use this temporary policy:

- The hospital must be treating COVID-19 patients,
- The hospital is unable to obtain the drug product(s) from other sources, including outsourcing facilities
- The drug product(s) are limited to only those listed in the FDA temporary policy,
- The BUD is assigned according to the FDA temporary policy,
- The hospital provides relevant information to the pharmacy within 30 days, and
- The compounding pharmacy notifies the state regulatory authority for compounding (board of pharmacy, generally) both in the state in which the compounding pharmacy is located as well as the state in which the hospital is located and obtains notification that the regulatory authority does not object to the provision of the drug products.

COMPOUNDING

Question: Does the Board have any recommendations concerning the possibility of shortages of garb and personal protective equipment (PPE)?

Answer: Yes. The Board issued guidance relating to this on March 9, 2020, which can be found here. Since the Board's initial issuance of this guidance, additional guidance has been issued by Critical Point, USP and FDA. The Board supports the use of PPE reuse and shortage guidance put forth by any of these organizations as it applies to your facility.

The Board strongly encourages compounding personnel to utilize the resources available at the Critical Point Peer Network where you can sign up for a Silver Subscription at no charge and access valuable information relating to compounding challenges resulting from the COVID-19 pandemic.

Additionally, USP issued an information resource that might be helpful: USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic. The Board is aware that the recommendations are slightly different from those provided by Critical Point. The Board is supportive of licensees making professional judgments in their individual situation to determine the best course of action to ensure product quality, public safety, and employee protection.

On April 10, 2020, FDA issued a Temporary Policy Regarding NonStandard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency which provides that it does not intend to take enforcement action regarding compliance with the insanitary conditions provision when drugs intended or expected to be sterile are compounded without standard PPE provided the compounder is compliant with the conditions identified in the temporary policy.

Question: Is it ok for my pharmacy to delay routine media-fill testing, gloved fingertip testing, and garbing technique observation in an effort to conserve garb?

Answer: Maybe. Since media-fill testing can reasonably be completed at the end of a compounding shift, this would not require additional, unnecessary use of garb and should not be delayed. If garbing is simply for the purpose of observing the garbing and aseptic technique of compounding personnel (unless for a newly trained compounder), the observer may consider remote observation (through a window, etc.) during normal compounding operations or, if that's not reasonable, testing could be delayed.

Question: Can my pharmacy compound prescription medications that are essentially copies of FDA-approved, commercially available products if they are on backorder or not available?

Answer: Yes. Board rule 657 IAC 20.12 currently authorizes a pharmacist to compound a drug that is otherwise commercially available when that product is not available due to a documented drug shortage or the drug is listed on the FDA Drug Shortages List. On March 25, 2020, FDA added hydroxychloroquine to Category 1 for compounding with bulk drug substances.

Question: Given shortages of hand sanitizer, can pharmacies, manufacturers, and outsourcing facilities compound and sell hand sanitizer products?

Answer: Yes. Board rules would ordinarily limit a pharmacy to dispensing compounded products only pursuant to a patient-specific prescription, but FDA recently published its Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency encouraging pharmacies to engage in such compounding. The Board will exercise enforcement discretion when pharmacies and outsourcing facilities engage in compounding of hand sanitizer in compliance with FDA guidance.

Additionally, USP issued an informational resource which might be helpful: Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic. On March 25, 2020, USP published this updated resource: Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic.

The Board has been alerted that PCCA has a formulation that is slightly different than the FDA guidance identifies. The Board is supportive of a pharmacy using a formulation by any nationally recognized compounding authority (FDA, PCCA, etc.) as long as the pharmacy or outsourcing facility is limiting the BUD to 30 days as recommended by WHO and USP.

As it relates to manufacturers who do not already have FDA approval to produce these products, FDA released *temporary* Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19). The Board will also exercise enforcement discretion with manufacturers which are producing hand sanitizers under FDA's Guidance.

Question: I have heard on the news about distilleries beginning to manufacture hand sanitizer. Is this legal?

Answer: At this time, FDA has issued *temporary* Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) which establishes that FDA will not take enforcement action against a firm for this activity *if* they are strictly following the guidance for formulation, documentation, and controls.

Question: Can my pharmacy implement remote verification of compounding activities?

Answer: Yes, see "**REMOTE PROCESSING**" section for information about systems requirements to implement product or staging verification during compounding operations.

Question: Will the board or the FDA be enforcing the FDA's "one mile radius" limitation set in its draft Guidance for compounding within a health system?

Answer: The FDA recently announced a policy clarification that its draft guidance for hospital and health system compounding is still in draft and is planned to be revised. As the Guidance has only been issued for public comment, it has not been implemented and FDA will not be enforcing a one mile radius for hospitals and hospital systems. As such, the Board will also not be enforcing a one mile radius limitation.

Question: Will the board or FDA be enforcing the federal law which specifies a 5% limit on interstate distribution of compounded drug products?

Answer: FDA recently announced a policy clarification that it will not be enforcing the federal 5% distribution limitation until such time as the Memorandum of Understanding can be finalized (FDA is in its final stages of making the MOU available) and states are allowed the opportunity to sign it. As such, the Board will also not be enforcing the 5% distribution limitation.

Question: What is the procedure for a pharmacy that wishes to provide compounded medications to a hospital without a patient-specific prescription under the FDA's Temporary Policy?

Answer: The FDA recently issued a Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (Updated Policy May 8 and again May 21) which authorizes 503A compounding pharmacies to distribute certain compounded drug products for use in hospitalized patients with COVID-19 without first obtaining a patient-specific prescription. The Temporary Policy identifies the specific drug products covered by the Policy as well as beyond-use-dating limitations for the compounded products, among other conditions. A pharmacy which intends to distribute non-patient specific compounded drug products pursuant to the FDA Temporary Policy must first notify the Board (via email to sue.mears@iowa.gov) and provide the following information:

- Pharmacy name and address,

- Iowa pharmacy license number, and
- Drug product(s) which the pharmacy intends to distribute.

Upon review of the notification and supporting documentation, Board staff will provide a response indicating if the Board does not intend to object to the pharmacy providing the drug product(s) to the hospital(s) without first obtaining a patient-specific prescription.

TELEHEALTH ENCOUNTERS / PRESCRIPTIONS ISSUED VIA TELEMEDICINE

Question: If an Iowa-located health system engages with prescribers located in another state to provide remote telehealth services to Iowa patients, is the prescriber required to obtain an Iowa CSA registration prior to issuing a controlled substance prescription?

Answer: Temporarily, no. Under Section Nine of the Governor's State of Public Health Disaster Emergency issued March 17, 2020 (and extended in subsequent Proclamations, under different sections, to continue through August 23), all implementing regulations establishing preconditions on the provision of telemedicine services have been temporarily suspended. As such, a prescriber would not be required to obtain an Iowa CSA prior to providing telemedicine services, including issuing a controlled substance prescription, to a patient located in Iowa. Once the Governor's declaration has been lifted, the Board's rules would be reinstated to require an Iowa CSA registration prior to issuing a controlled substance prescription via telemedicine to a patient located in Iowa.

DEA has also announced that, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.

BOARD GENERAL OPERATIONS AND MEETINGS

Question: Will the Board of Pharmacy offices remain open for business and will the hours of operation remain the same?

Answer: The Board office is currently closed to the public. A mail drop box has been placed in the front vestibule in which items for Board staff may be placed. Licensees and registrants are asked to utilize the Board's Online Services to the extent possible. Questions can be directed to Board Staff. The Board's hours of operation will remain the same at this time.

Question: Will the Board's regularly scheduled meetings (Open session Board meetings, Rules Committee, Prescription Monitoring Program Advisory Council, and Monitoring Program for Pharmacy Professionals) continue to be held?

Answer: At this time, the Board is postponing any in-person meeting that is currently scheduled through the end of July. As necessary, the Board may hold teleconference meetings to handle the business of the Board.

Question: Will I be determined to be noncompliant with my IMP3 contract if I am unable to attend meetings or practitioner appointments that are included in my contract?

Answer: Not if you are in routine communication with the IMP3 Case Manager to keep her updated on your situation.

BOARD LICENSING OPERATIONS

Question: Will licensees be allowed to continue operating or practicing if the Board is unable to process renewals?

Answer: Yes. The Board's current rules allow continuation of operations or practice during a 30 day grace period while a renewal application is being processed. Board licensing staff will continue to process applications and the Board does not anticipate any excursion from its normal application processing times. Licensees and registrants are encouraged to utilize the Board's Online Services.

Question: Will licensees and registrants already licensed/registered with the Board be allowed to continue practicing after their license/registration expires as a result of their inability to timely renew their license/registration due to the COVID-19 pandemic?

Answer: Yes, under Governor Reynolds' Proclamations, licensees and registrants whose license/registration expires and who are unable to renew between March 22 and August 23 will be authorized to continue practice. The Board reminds licensees and registrants that renewal is available online, which processes in a matter of minutes, if you have all necessary documentation available. Board staff continues to operate and does not anticipate any delays in processing. On March 27, the Board issued its Response to the Governor's Proclamation which provides additional information. In response to the Governor's April 2 Proclamation, the Board issued this Guidance on April 6, 2020. In response to the Governor's April 27 Proclamation, the Board issued this Response. In response to the Governor's May 26 Proclamation, the Board issued this Response. In response to the Governor's June 25 Proclamation, the Board issued this Response. The Board will continue to implement the Governor's Proclamation as identified in prior responses when extended or discontinue when the Proclamation is expired or terminated.

Question: Will the Board process applications for new licenses and registrations in a normal manner?

Answer: At this time, the Board does not anticipate any excursion from its normal processing, but as COVID-19 continues to present incredible challenges, Board staff may need to make adjustments in the Board's operations accordingly. The Board recognizes that new license/registration applications may be submitted as a means to assist with the pandemic in Iowa, so Board staff will make every effort to timely process new applications.

BOARD VARIANCE/WAIVER REQUEST REVIEWS

Question: Will the Board continue to process variance/waiver requests that require Board approval?

Answer: Pursuant to the Board's Statement on Enforcement Discretion issued March 23, 2020, the Board is essentially waiving all non-essential rules relating to the practice of pharmacy with the expectation that all licensees and registrants operate at a minimum standard of care ("standard of care" meaning that which would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience). The Board will continue to review any submitted waiver/various requests during its regular open session meetings.

Question: If we have submitted a request to extend an existing waiver request but the Board is unable to consider the request due to adjustments in meetings and agendas, can we continue to operate under the expired waiver?

Answer: Yes. It's possible the waiver that had been granted would be subject to the Board's generalized declaration of exercising enforcement discretion in the practice of pharmacy. If the waiver applied to some other rule that somehow would not be covered by the Board's Statement, the licensee may continue to operate under the prior waiver until such time that the Board can meet to consider the renewal request.

Question: What should licensees do if they are unable to meet the granted delay in compliance with USP Chapter facility requirements due to delays caused by responding to the COVID-19 pandemic?

Answer: The Board's delayed compliance committee will consider extension requests for any granted delay that will expire within 90 days. The Board expects that licensees will attempt to comply with their granted delay, but acknowledges that pandemic circumstances may affect labor and financial resources. The committee will consider any request for extension that includes an adjusted timeline. Requests should be sent by email to Christie Carlson at christie.carlson@iowa.gov who will handle submission for consideration. Licensees may continue to send requests after pandemic resolution, if needed.